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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,920	02/20/2002	James R. Uhl	07039-393001	2201
26191	7590	06/02/2004	EXAMINER	
FISH & RICHARDSON P.C. 3300 DAIN RAUSCHER PLAZA 60 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/081,920

Applicant(s)

UHL ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/6/04 and 3/19/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on March 22, 2004.

Claims 1-8 are pending.

#### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,882,943 to Aldeen in view of US patent 4,591,486 to Eberle.

Aldeen discloses a kit and method for processing microorganisms (parasites) from human and animal specimens. The kit comprises a filtration apparatus and preservation fluid dispenser. Referring to figure 2, the filtration apparatus comprises a specimen receptacle (110) and a collection receptacle (150). The specimen receptacle holds an original human or animal sample. The collection receptacle holds the portion of the sample from the specimen receptacle that bypasses the porous bottom (140) of the specimen receptacle. The specimen receptacle

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includes an open end (102), large enough to receive a sample transfer device. The specimen receptacle also includes an open bottom end having a porous material having holes small enough so as to not allow the specimen transfer device to pass through. The collection receptacle includes an open end into which the specimen receptacle is received and a closed end where the final sample is collected. The preservation fluid is a buffer agent or other agent for preserving the sample. The preservation fluid is contained with a dispenser (packaging). With respect to the method for processing microorganisms, Aldeen discloses mixing a sample with a preservation solution and transferring the solution into the above described filtration apparatus. At col. 10, lines 14-22, the reference teaches that the specimen may be collected on a specimen transferring device (688), which is placed into the dispenser which may be adapted to engage open end (102) of the specimen receptacle, without the possibility of exposing the user to the specimen. See figure 8. Next, the entire filtration apparatus is centrifuged to produce a supernatant and a pellet in said collection receptacle (col. 45, line 54 – col. 46, line 26). With regard to the microorganisms to be processed, Aldeen discloses bacterium such as *E. coli*.

Aldeen differs from the instantly claimed invention in that Aldeen discloses a spatula as the specimen transferring device, whereas the instant claims recite the use of a swab.

Eberle teaches a device for separating a sample into a more useful portion for analysis. The device of Eberle comprises a tube separated into sections. Eberle teaches introducing sample into the upper portion of the centrifuge tube by way of a cotton swab. The swab containing the sample is centrifuged. It is conventional to use a swab as a specimen collection/transferring tool, as is taught by Eberle. A swab allows sample from discrete locations to be collected in sufficient amounts for analysis. It would have been obvious to one of ordinary skill in the art to substitute the spatula of Aldeen with a swab to collect and transfer

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the microorganism sample because of its ability to collect sample in a manner sufficient for analysis.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Aldeen and Eberle.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aldeen and Eberle as applied to claims 1-5, 7 and 8 above, and further in view of US Patent 5,498,395 to Moore, Jr. et al.

Neither Aldeen and Eberle disclose a sterile containment vessel.

Moore, Jr. et al teaches the importance using a sterile centrifuge tubes for human samples. It would have been obvious to one of ordinary skill in the art to use sterile centrifuge tubes in Aldeen to alleviate the possibility of contaminating the user or contaminating the sample itself.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Aldeen, Eberle and Moore, Jr. et al.

### ***Response to Arguments***

5. Applicant's arguments filed March 22, 2004 have been fully considered but they are not persuasive. With respect to the obviousness rejection over Aldeen in view of Eberle, Applicants argue 1) Aldeen does not teach an aperture such as that claimed in claims 1 and 4 of the instant invention and 2) the specimen transferring device of Aldeen is not centrifuged.

With respect to the aperture, Applicants' state that the claimed aperture is "quite

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6.       different" from the porous filters taught by Aldeen. Applicants reasons that the pores in the filters of Aldeen are clearly defined and the aperture of instant invention, according to the specification, is 0.1 mm – 3.0 mm. First, the Examiner would like to point out that the claims do NOT recite any particular size for the aperture. The claims merely state that the aperture is small enough so as to not allow the swab to pass through, but large enough to allow microorganisms to pass through. Aldeen discloses that the porous filters only allow ova and parasites to pass through. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Even if Applicants were to incorporate the specific size of the aperture into the claims, Aldeen would still read on those limitations. Aldeen clearly defines the pores to be about 180 – 295 micrometers (col. 5, lines 54-62 of Aldeen). When converted to millimeters, Aldeen teaches 0.18 – 0.295 millimeters. Thus, the sizes of the holes taught by Aldeen fall within the range of the size of the aperture (0.1 mm – 3.0 mm) defined by Applicants' specification.

With respect to the centrifuging the swab itself, the Examiner pointed out that Eberle teaches that a swab containing the sample of interest may be added to a centrifuge tube, along with a test medium and centrifuged, with the swab remaining in the tube (col. 4, lines 3-21). In centrifuging the swab with the tube, the user is assured that all components of interest in the sample being processed are extracted and separated during the centrifugation process. Applicants argue that if the swab were centrifuged in the assembly of Aldeen, then the swab would damage the filter. Applicants provided no basis for this conclusion. In fact, Aldeen teaches that the filters may be supported by a support screen (565). It is the position of the

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Examiner that the support screen would provide extra security for the filters and prevent any damage during centrifugation.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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